

Application No.: 10/695,297  
Response to Office Action of February 9, 2007  
Attorney Docket: MCROD-002CB

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### REMARKS

#### *Summary of Office Action*

In the Office Action, the Examiner maintained the rejection of Claims 1 and 5 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Number 5,405,784 issued to Van Hoegaerden (hereinafter "Van"). The Examiner also rejected Claims 2-4 and 6-8 under 35 U.S.C. § 103(a) as being unpatentable over Van in view of U.S. Patent Number 5,981,298 issued to Chudzik et al. (hereinafter "Chudzik") and the Triage Panel for Drugs of Abuse reference (hereinafter "Panel").

#### *Summary of Amendment*

Upon entry of the present Amendment, Claims 1 and 3-8 will have been amended. Additionally, new Claims 9 and 10 will have been added. As such, Claims 1-10 remain currently pending. By the present Amendment, Applicant submits that the rejections have been overcome and respectfully requests reconsideration of the outstanding Office Action.

#### *Applicant's Response*

##### 1. Section 102(b) Rejection of Claims 1 and 5

The Examiner again submits that Van discloses fluorescent latex beads having more than one antiligand fixed to their surface and that the antiligands may be specific to more than one substance. *Office Action*, Page 2. The Examiner then admits that Van does not teach that the antiligands are ligand analogs. *Id.* The Examiner instead asserts that they are the same since Van defines the antiligand to be a molecular structure capable of recognizing and binding specifically to the organic, biological, or medicinal substances to be detected. *Id.* at 2-3. Finally, the Examiner submits that Van teaches that the beads are suitable for direct, indirect sandwich, or competitive assays. *Id.* at 3.

Applicant's independent Claim 1 as currently amended recites, *inter alia*, "A dye for use in detecting the presence of two dissimilar ... ligands ... utilizing receptors specific for said ... ligands comprising: a particulate dye component; a first ligand analog covalently

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bound to a protein; a second ligand analog covalently bound to a protein, wherein said second ligand analog is *dissimilar* to the first ligand analog; wherein said first ligand analog and covalently bound protein and said second ligand analog and covalently bound protein are absorbed upon said particulate dye; and wherein said particulate dye ... is operative to bind with receptors for both said ... ligands."

Van specifically requires, "... *the formation of complexes* by contact of the specimen with fluorescent beads on which is fixed at least one suitable *antiligand*, under conditions suitable for the appearance of an agglutination or for the inhibition of an agglutination..." *Column 5, lines 19-24* (emphasis added). As the Examiner admitted, Van defines an antiligand as, "... a molecular structure capable of recognizing and binding specifically to the organic, biological, or medicinal substances to be sought ..." *Column 3, lines 23-26*.

As is currently understood, in no way does Van teach or suggest a dye containing *two different ligand analogs*. Van *may* disclose fluorescent beads containing two different *antiligands* that are capable of binding to the desired ligands. Furthermore, as the Examiner pointed out, Van discloses in Example 5 the use of fluorescent beads containing *a single ligand analog*. However, Van only discloses the use of fluorescent beads for use in agglutination processes. For example, Example 5 utilizes both a ligand analog coated fluorescent bead and an antiligand coated fluorescent bead such that presence of the desired ligand results in the inhibition of agglutination between the ligand analog coated bead and the antiligand coated head. If one were to drastically modify the teachings of Van, as the Examiner proposes, and coat a fluorescent bead with two dissimilar ligand analogs and then utilize the agglutination process of Van, one would be unable to distinguish which ligand is present or absent in a sample since the presence of either ligand or no ligands in the sample would result in agglutination, while *only the presence of both ligands would inhibit* the agglutination reaction. As such, the Examiner's proposed modification to Van would result in a meaningless test that would *only indicate whether both ligands were present in a sample*.

Additionally, as amended, Applicant's Claim 1 requires that the ligand analogs be covalently bound to a protein and that the ligand analogs and protein are absorbed on the dye particulate. As is currently understood, Van does not disclose or suggest the use of

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covalently binding ligand analogs to a protein while absorbing the ligand analogs and the protein to the particulate dye.

As such, and because Van fails to disclose the above-noted features of the present invention, Applicant submits that Van fails to disclose each and every recited feature of the present invention as recited in independent Claim 1.

Accordingly, Applicant submits that the Examiner has failed to provide an adequate evidentiary basis to support the rejection under 35 U.S.C. § 102(b) and that the present rejection of Claim 1 is improper and should be withdrawn.

Applicant further submits that the Claims 2-10 are allowable at least for the reason that these claims depend on allowable independent Claim 1 and because these claims recite additional features that further define the present invention. For example, Claim 3 requires that the ligand analogs comprise molecules of the ligand to be detected themselves. Furthermore, newly added Claim 10 requires that the protein utilized comprise bovine serum albumin. Applicant respectfully submits that these further elements are not disclosed or suggested in any of the references of record and are therefore independently allowable even should the Examiner refuse allowance of independent Claim 1.

## 2. Section 103(a) Rejection of Claims 2-4 and 6-8

The arguments presented above in regard to Van are incorporated herein by reference. Applicant respectfully submits that independent Claim 1 has been shown above to be allowable and that these claims are likewise allowable for reciting further independently patentable features of the present invention.

### *Conclusion*

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. §§ 102 and 103, and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention.

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's

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invention as recited in each of Claims 1-10. The applied references of record have been discussed and distinguished, while significant claim features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 7/3/07

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